DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 29, 2014

3D Medical Concepts, LLC
Ms. Beverly Laird
1061 Morgan Park Road
Pelham, Alabama 35242

Re: K140649
Trade/Device Name: Vectrix External Fixator
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: NDK
Dated: October 20, 2014
Received: October 27, 2014

Dear Ms. Laird:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*

K140649

Device Name
Vectrix External Fixator

Indications for Use *(Describe)*

The Vectrix External Fixator is indicated for use in cases in which external fixation is necessary for the treatment of long- and short-bone trauma and reconstruction in adult and pediatric patients, including limb lengthening, pseudarthroses, infected fractures, distraction, arthrodesis, and severe open fractures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

**3D Medical External Fixator**

## 510(k) Summary

**Company Name:** 3D Medical Concepts, LLC
1061 Morgan Park Rd.
Pelham, AL 35124
Phone: (205) 987-0935
Fax: (205) 987-0936

**Contact Name:** Dr. Beverly Laird

**Date Prepared:** October 20, 2014

**Trade Name:** Vectrix External Fixator

**Common Name:** External Fixation Device

**Classification:** Class II (21 CFR 888.3040)
Smooth or Threaded Metallic Bone Fixation Fastener

**Product Code:** NDK

**Predicate Device:** Torus External Fixation System (K925635)

**Device Description:** The Vectrix External Fixator is a comprehensive and modular external fixator, the design of which is based on a ball collet pin clamp system and consists of:

- 6AL-4V titanium and/or 304SS stainless steel spline rod (0.125, 0.25, and 0.375 inches in diameter)
- 6AL-4V titanium and/or 316L stainless steel self-tapping, threaded fixation pins (5.0 mm and 4.0 mm thread diameter pins with thread lengths from 25 mm to 75 mm, varying in 5 mm increments; and 3.5 mm thread diameter pins with thread lengths of 15 mm)
- Titanium pin clamps
- Titanium ball collets
- Titanium collet caps
- Titanium drive knob
- Titanium drive screw

Fixation pins are percutaneously inserted into the bone segments and secured with pin clamps to the external spline rod. The choice of thread diameter and length is made by the surgeon on a case-by-case basis. The ball and collet design allows extensive pin rotation and, thus, pin placement freedom.

The system can be assembled in three sizes, determined by the spline rod size. Furthermore, elements of the system may be combined in a wide range of configurations as needed to achieve the external fixation structure best suited for each

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| | patient. The drive screw and drive knob can also be added to the spline rod constructs of each size to mediate bone compression and distraction for limb reconstruction. |
| **Indications for Use:** | The Vectrix External Fixator is indicated for use in cases in which external fixation is necessary for the treatment of long- and short-bone trauma and reconstruction in adult and pediatric patients, including limb lengthening, pseudarthroses, infected fractures, distraction, arthrodesis, and severe open fractures. |
| **Substantial Equivalence:** | The design, indications, materials, and characteristics of the Vectrix External Fixator are substantially equivalent to the Torus External Fixation System (K925635). |
| **Technological Characteristics Comparison:** | The Vectrix External Fixator was designed in conformance with ASTM F136 (Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI Alloy for Surgical Implant Applications), ASTM F138 (Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673), and ASTM F86 (Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants). All requirements were met for these standards. |
| **Performance Data:** | Non-clinical interconnection testing per ASTM 1541-02, Standard Specification and Test Methods for External Skeletal Fixation Devices (A2.8.4 Pin/Clamp Eccentric Loading), was conducted to confirm that the connection mechanisms of the Vectrix External Fixator are equivalent to those of the Torus External Fixation System (K925635). |